This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problems Mailbox.

THIS PAGE BLANK (USPTO)

PCT/ SE 99 / 00416

Intyg Certificate

SE99/416



Härmed intygas att bifogade kopior överensstämmer med de handlingar som ursprungligen ingivits till Patent- och registreringsverket i nedannämnda ansökan.

Ansökan ingavs ursprungligen på engelska.

This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

The application was originally filed in English.

- (71) Sökande Astra AB, Södertälje SE Applicant (s)
- (21) Patentansökningsnummer 9800897-2 Patent application number
- (86) Ingivningsdatum
 Date of filing

Stockholm,

1998-03-17

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

För Patent- och registreringsverket

1999-04-14

For the Patent- and Registration Office

Evy Morin

Avgift Fee

10

15

25

30

INHALATION DEVICE

The present invention relates to a blister pack assembly for a powder inhaler and a powder inhaler comprising the same.

One such powder inhaler is disclosed in WO-A-97/40876. This inhaler comprises a blister pack element having blisters therein which include powder containing medicament, a support unit for supporting the same and a suction tube through which powder is inhaled. In use, the suction tube is inserted into one of the blisters and the powder in the respective blister is inhaled therethrough.

Whilst this known powder inhaler functions perfectly adequately, it is an aim of the present invention to provide a powder inhaler, which for the same number of doses, is of smaller dimension.

Accordingly, the present invention provides a blister pack assembly for a powder inhaler, comprising a body comprising first and second surfaces each having a plurality of blisters therein which include powder containing medicament.

20 Preferably, the body further comprises a supporting member which supports the first and second surfaces. In a preferred embodiment the supporting member comprises a frame.

Preferably, the first and second surfaces are oppositely directed. More preferably, the first and second surfaces are substantially parallel. In a preferred embodiment the blisters in the first and second surfaces are arranged such that the blisters in the first surface are disposed in one or both of spaces between and adjacent the blisters in the second surface.

It will be appreciated that a blister pack assembly and hence an inhaler of minimum thickness is achieved by arranging the blisters in the first surface so as to be disposed in spaces between and adjacent the blisters in the second surface.

25

30

In one embodiment the first and second surfaces are defined by separate elements.

In another embodiment the first and second surfaces are defined by a single element. In a preferred embodiment the single element is a folded element.

Preferably, the blister pack assembly further comprises a suction tube having a part adapted for insertion into a respective one of the blisters and an inhalation channel through which powder is in use inhaled.

Preferably, the body further comprises holding means for holding the suction tube when not in use. In one embodiment the holding means comprises at least one part to which the suction tube can be clipped.

- Preferably, the blister pack assembly further comprises connecting means for connecting the suction tube to the body so as to prevent the suction tube from being separated from the body. In a preferred embodiment the connecting means is a line which may be formed of a resilient material.
- Preferably, the body further comprises a track and the connecting means is provided with an element which is captively held within the track and movable between first and second positions. In a preferred embodiment the track is configured such that with the element in one of the first and second positions the connecting means is substantially disposed within the track.

Preferably, the body further comprises biasing means for biasing the element towards the one of the first and second positions.

The present invention also provides a powder inhaler which in its simplest embodiment comprises the above-described blister pack assembly and suction tube.

20

25

Preferably, the inhaler further comprises a support unit for supporting the blister pack assembly, the support unit including a plurality of guide portions for guiding the suction tube into respective blisters in the first and second surfaces.

More preferably, the support unit comprises a housing in which the body of the blister pack assembly is removably received, with at least one wall of the housing including the guide portions.

- Yet more preferably, the body of the blister pack assembly has a rotational symmetry such that in a first rotational position the first surface thereof is disposed adjacent the at least one wall of the housing and in a second rotational position the second surface thereof is adjacent the at least one wall of the housing.
- Preferably, the support unit further comprises a cover member hingeably mounted to the housing, the cover member enclosing the suction tube and the guide portions when closed.

It will be appreciated that by providing the blisters in separate surfaces the powder inhaler of the present invention is particularly suited to use with two different medicaments, one medicament being included in the blisters of the first surface and the other medicament being included in the blisters of the second surface. In addition, with this construction, a user is far less likely accidentally to take the wrong medicament as compared to a construction where blisters including different medicaments are provided in a single surface and the user has to ensure that the suction tube is inserted into the correct blister in the one surface.

Preferred embodiments of the present invention will now be described hereinbelow by way of example only with reference to the accompanying drawings, in which:

Figure 1 illustrates a perspective view of a powder inhaler in accordance with a first embodiment of the present invention;

Figure 2 illustrates a perspective view of the blister pack assembly of the inhaler of Figure 1;

Figure 3 illustrates a plan view of the blister pack assembly of Figure 2;

Figure 4 illustrates a sectional view (along section A-A in Figure 3) of the blister pack
assembly of Figure 2;

Figure 5 illustrates a side view of the supporting member of the body of the blister pack assembly of Figure 2 (with the suction tube illustrated in phantom);

Figure 6 illustrates a plan view of the supporting member of the body of the blister pack assembly of Figure 2 (with the suction tube illustrated in phantom);

Figure 7 illustrates the first blister pack element of the body of the blister pack assembly of Figure 2 when viewed from below;

Figure 8 illustrates the second blister pack element of the body of the blister pack assembly of Figure 2 when viewed from above;

Figure 9 illustrates a perspective view of the support unit of the inhaler of Figure 1;

Figure 10 illustrates a plan view of the support unit of Figure 9;

Figure 11 illustrates a perspective view of the blister pack assembly of a powder inhaler in accordance with a second embodiment of the present invention;

20

25

15

30

Figure 12 illustrates a plan view of the blister pack assembly of Figure 11;

Figure 13 illustrates a sectional view (along section B-B in Figure 12) of the blister pack assembly of Figure 11 (with the suction tube illustrated in phantom);

Figure 14 illustrates in sectional view the step of fitting together the foldable element comprising the first and second blister pack elements and the supporting member of the body of the blister pack assembly of Figure 11 (with the suction tube illustrated in phantom);

Figure 15 illustrates a plan view of the foldable element of the body of the blister pack assembly of Figure 11 in the unfolded configuration;

Figure 16 illustrates a perspective view of the blister pack assembly of a powder inhaler in accordance with a third embodiment of the present invention;

Figure 17 illustrates a perspective view of a powder inhaler in accordance with a fourth embodiment of the present invention;

Figure 18 illustrates a perspective view of the blister pack assembly of the inhaler of Figure 17;

Figure 19 illustrates a plan view of the blister pack assembly of Figure 18;

Figure 20 illustrates a plan view of the supporting member of the body of the blister pack assembly of Figure 18 (with the suction tube and associated component parts illustrated in phantom);

Figure 21 illustrates a plan view of the suction tube and associated component parts of the blister pack assembly of Figure 18;

10

15

20

25

30

Figure 22 illustrates in perspective view the step of fitting together the foldable element comprising the first and second blister pack elements and the supporting member of the body of the blister pack assembly of Figure 18;

Figure 23 illustrates a plan view of the foldable element of the body of the blister pack assembly of Figure 18 in the unfolded configuration;

Figure 24 illustrates a perspective view of the support unit of the inhaler of Figure 17; and

Figure 25 illustrates a plan view of the support unit of Figure 24.

Figure 1 illustrates a powder inhaler in accordance with a first embodiment of the present invention. The powder inhaler comprises a support unit 1 and a blister pack assembly 2 which is removably mounted thereto and comprises a body 3 and a suction tube 4.

As illustrated in Figure 2, the body 3 comprises a supporting member 6, in this embodiment in the form of a frame, and first and second blister pack elements 8, 10 fixed, for example, by an adhesive, to the supporting member 6. The first and second blister pack elements 8, 10 comprise a thin sheet 8a, 10a having a plurality of blisters 8', 10' formed therein and a thin film 8b, 10b covering the openings to the blisters 8', 10', each of the blisters 8', 10' including a dose of powder containing medicament. Figures 7 and 8 illustrate respectively the first blister pack element 8 when viewed from below and the second blister pack element 10 when viewed from above, with the blister pack assembly 2 oriented as illustrated in Figure 2. In this embodiment the first and second blister pack elements 8, 10 are separate and are fixed to the supporting member 6 so as to present first and second oppositely-directed parallel surfaces. Further, in this embodiment, the first and second blister pack elements 8, 10 are configured, as illustrated in Figures 3 and 4, such that the blisters 8' in the first blister pack element 8 are located in spaces between and adjacent the blisters 10' in the second blister pack element 10. In this way, the thickness of

10

15

20

25

30

the blister pack assembly 2 and hence the inhaler is kept to a minimum for blisters of a particular dimension. In this embodiment the supporting member 6 includes first and second projections 12, 14 disposed to one side thereof and between which the suction tube 4 is clipped.

The suction tube 4 is an elongate member having an inhalation channel 15 extending longitudinally therethrough. One end 4a of the suction tube 4 is provided with a cutting edge 16 for rupturing the film 8b, 10b covering a respective one of the blisters 8', 10' on insertion of the suction tube 4 into the same. The other end 4b of the suction tube 4 acts as a mouthpiece which is gripped by the lips of a user during inhalation.

The support unit 1 comprises a housing 17 having a cavity 18 into which the body 3 of the blister pack assembly 2 is removably mounted. In a preferred embodiment the housing 17 and the body 3 are provided with engaging parts (not illustrated) by which the blister pack assembly 2 is fastened by clipping to the housing 17. One of the major surfaces 17' of the housing 17 includes a plurality of openings 19 therein which have the same arrangement as the blisters 8', 10' in the first and second blister pack elements 8, 10 of the body 3. In this embodiment the body 3 has rotational symmetry such that, with either the first or the second blister pack elements 8, 10 adjacent the one surface 17' of the housing 17, the blisters 8', 10' therein are located at the openings 19. In a preferred embodiment the support unit 1 further comprises a cover member (not illustrated) which is hingeably mounted to the housing 17 so as to enclose the suction tube 4 and the openings 19 in the one surface 17' of the housing 17 when closed, thereby preventing debris from gathering in the suction tube 4 and/or the openings 19 and the accidental rupturing of any of the blisters 8', 10' by a foreign object such as a key when kept in a pocket.

In use, a user first inserts a blister pack assembly 2 into the cavity 18 in the housing 17, with one of the blister pack elements 8, 10, in this embodiment the first blister pack element 8, adjacent the one surface 17' of the housing 17. The user then unclips the suction tube 4 from between the projections 12, 14 and inserts the suction tube 4 through a

15

20

25

30

respective opening 19 in the one surface 17' of the housing 17 and into an unused blister 8'; with the opening 19 acting as a guide and the cutting edge 18 of the suction tube 4 rupturing the film 8b covering the respective blister 8'. With the suction tube 4 located in the blister 8', the user then grips the free end 4b of the suction tube 4 in the lips and inhales so as to withdraw the dose of powder from the blister 8' and deliver the same into the lungs. After inhalation, the user clips the suction tube 4 back between the projections 12, 14. This pattern of use can be repeated until all of the blisters 8' in the first blister pack element 10 have been used. When all of the blisters 8' in the first blister pack element 8 have been used, the user then withdraws the blister pack assembly 2 from the housing 17, rotates the same through 180 degrees about the axis of insertion and re-inserts the body 3 of the blister pack assembly 2 into the cavity 18 in the housing 17, with the second blister pack element 10 adjacent the one surface 17' of the housing 17 in which the openings 19 are provided. In this way, the blisters 10' in the second blister pack element 10 are available for use. When all of the blisters 10' in the second blister pack element 10 have been used, the user then withdraws the blister pack assembly 2 from the housing 17, disposes of the same and inserts a new blister pack assembly 2 into the cavity 18 in the housing 17. Where the blisters 8' in the first blister pack element 8 include a different medicament to the blisters 10' in the second blister pack element 10, the blister pack assembly 2 is withdrawn, rotated and re-inserted as and when required to expose the respective blisters 8', 10' for use.

Figure 11 illustrates the blister pack assembly 2 of a powder inhaler in accordance with a second embodiment of the present invention. This inhaler is structurally quite similar to the inhaler of the above-described first embodiment, and for this reason, and in order to avoid unnecessary duplication of description, only the structural differences will be described in detail and reference is made to the preceding description of the inhaler of the first embodiment. This inhaler differs from the inhaler of the above-described first embodiment only in the construction of the blister pack assembly 2. In this embodiment the first and second blister pack elements 8, 10 are sections of a single element 20 which includes a hinge section 22 between the first and second blister pack elements 8, 10. As

10

15

20

25

30

illustrated in Figure 14, the single element 20 is folded about the hinge section 22 so as to present first and second oppositely-directed parallel surfaces on fitting to the supporting member 6. Operation of this inhaler is the same as for the inhaler of the above-described first embodiment.

Figure 16 illustrates a powder inhaler in accordance with a third embodiment of the present invention. This inhaler is structurally almost identical to the inhaler of the above-described first embodiment, and for this reason, and in order to avoid unnecessary duplication of description, only the structural differences will be described in detail and reference is made to the preceding description of the inhaler of the first embodiment. This inhaler differs form the inhaler of the above-described first embodiment only in further comprising a line 24 connecting the suction tube 4 and the body 3 so as to prevent the suction tube 4 from being separated from the body 3 and subsequently lost. In this embodiment the line 24 is formed of a plastics material such as nylon. In another embodiment the line 24 could be formed of a resilient material. Operation of this inhaler is the same as for the inhaler of the above-described first embodiment.

Figure 17 illustrates a powder inhaler in accordance with a fourth embodiment of the present invention. This inhaler is structurally similar to the inhaler of the above-described second embodiment, and for this reason, and in order to avoid unnecessary duplication of description, only the structural differences will be described in detail and reference is made to the preceding description of the inhaler of the second embodiment. This inhaler differs form the inhaler of the above-described second embodiment in further comprising a line 26, one end of which is fixed to the suction tube 4 and the other end of which is provided with an element 28 of larger dimension than the line 26, in that the supporting member 6 of the body 3 includes an elongate slot 30 which in this embodiment extends from the edge of the supporting member 6 to which the suction tube 4 is clipped, the opposing surfaces of which slot 30 include respective grooves 32 which define a track in which the element 28 is captively held, and in that the first and second blister pack elements 8, 10 each include elongate slots 34 which extend from the free ends thereof towards the hinge section 22 in a

15

20

25

position corresponding to the slot 30 in the supporting member 6 so as thereby to allow the line 26 to pass therethrough. This inhaler further differs from the inhaler of the above-described second embodiment in that the one surface 17' of the housing 17 in which the openings 19 are provided further includes an elongate slot 36 which extends from the open towards the closed end of the cavity 18 in a position corresponding to the slot 30 in the supporting member 6 so as thereby to allow the line 26 to pass therethrough.

Operation of this inhaler is much the same as for the inhaler of the above-described second embodiment. In use, a user unclips the suction tube 4 from between the projections 12, 14 and draws the suction tube 4 away from the body 3, thereby withdrawing the line 26 out of the slot 30. The user then inserts the one end 4a of the suction tube 4 through a respective opening 19 in the one surface 17' of the housing 17 and into an unused blister 8', 10'; with the opening 19 acting as a guide and the cutting edge 18 of the suction tube 4 rupturing the film 8b, 10b covering the respective blister 8', 10'. With the suction tube 4 located in the blister 8', 10', the user then grips the free end 4b of the suction tube 4 in the lips and inhales so as to withdraw the dose of powder from the blister 8', 10' and deliver the same into the lungs. After inhalation, the user clips the suction tube 4 back between the projections 12, 14, in so doing ensuring that the line 26 is fed back into the slot 30. In this embodiment the line 26 is formed of a plastics material, such as nylon, of sufficient rigidity that the line 26 can be fed easily into the slot 30. In another embodiment, in order to assist in feeding the line 26 into the slot 30, the element 28 could be formed of a relatively dense material, such as a metal, whereby the weight of the element 28 causes the line 26 to be drawn into the slot 30. In yet another embodiment the line 26 could be formed of a resilient material so as to cause the line 26 to be drawn actively into the slot 30. In still yet another embodiment a biasing means (not illustrated), such as a tension spring, could be provided between the closed end of the slot 30 and the element 28 so as to cause the line 26 to be drawn actively into the slot 30.

Finally, it will be understood by a person skilled in the art that the present invention is not limited to the described embodiments but can be modified in many different without departing from the scope of the invention as defined by the appended claims.

15

25

CLAIMS

- 1. A blister pack assembly for a powder inhaler, comprising a body (3) comprising first and second surfaces each having a plurality of blisters (8', 10') therein which include powder containing medicament.
- 2. The blister pack assembly of claim 1, wherein the body (3) further comprises a supporting member (6) which supports the first and second surfaces.
- 3. The blister pack assembly of claim 2, wherein the supporting member (6) comprises a frame.
 - 4. The blister pack assembly of any of claims 1 to 3, wherein the first and second surfaces are oppositely directed.
 - 5. The blister pack assembly of claim 4, wherein the first and second surfaces are substantially parallel.
- 6. The blister pack assembly of claim 4 or 5, wherein the blisters (8', 10') in the first and second surfaces are arranged such that the blisters (8') in the first surface are disposed in one or both of spaces between and adjacent the blisters (10') in the second surface.
 - 7. The blister pack assembly of any of claims 1 to 6, wherein the first and second surfaces are defined by separate elements (8, 10).
 - 8. The blister pack assembly of any of claims 1 to 6, wherein the first and second surfaces are defined by a single element (20).
- 9. The blister pack assembly of claim 8, wherein the single element (20) is a folded element.

15

25

- 10. The blister pack assembly of any of claims 1 to 9, further comprising a suction tube (4) having a part (16) adapted for insertion into a respective one of the blisters (8', 10') and an inhalation channel (15) through which powder is in use inhaled.
- 11. The blister pack assembly of claim 10, wherein the body (3) further comprises holding means for holding the suction tube (4) when not in use.
- 12. The blister pack assembly of claim 11, wherein the holding means comprises at least one part (12, 14) to which the suction tube (4) can be clipped.
 - 13. The blister pack assembly of any of claims 10 to 12, further comprising connecting means for connecting the suction tube (4) to the body (3) so as to prevent the suction tube (4) from being separated from the body (3).
 - 14. The blister pack assembly of claim 13, wherein the connecting means is a line (24; 26).
- 15. The blister pack assembly of claim 14, wherein the line (24; 26) is formed of a resilient material.
 - 16. The blister pack assembly of any of claims 13 to 15, wherein the body (3) further comprises a track and the connecting means is provided with an element (28) which is captively held within the track and movable between first and second positions.
 - 17. The blister pack assembly of claim 16, wherein the track is configured such that with the element (28) in one of the first and second positions the connecting means is substantially disposed within the track.

10

20

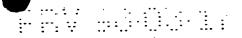
- 18. The blister pack assembly of claim 17, wherein the body (3) further comprises biasing means for biasing the element (28) towards the one of the first and second positions.
- 19. A powder inhaler comprising the blister pack assembly of any of claims 10 to 18.
- 20. The powder inhaler of claim 19, further comprising a support unit (1) for supporting the blister pack assembly, the support unit (1) including a plurality of guide portions (19) for guiding the suction tube (4) into respective blisters (8', 10') in the first and second surfaces.
- 21. The powder inhaler of claim 20, wherein the support unit (1) comprises a housing (17) in which the body (3) of the blister pack assembly is removably received, with at least one wall (17') of the housing (17) including the guide portions (19).
- 22. The powder inhaler of claim 21, wherein the body (3) of the blister pack assembly has a rotational symmetry such that in a first rotational position the first surface thereof is disposed adjacent the at least one wall (17') of the housing (17) and in a second rotational position the second surface thereof is adjacent the at least one wall (17') of the housing (17).
 - 23. The powder inhaler of claim 21 or 22, wherein the support unit (1) further comprises a cover member hingeably mounted to the housing (17), the cover member enclosing the suction tube (4) and the guide portions (19) when closed.

15

ABSTRACT

INHALATION DEVICE

A blister pack assembly for a powder inhaler and a powder inhaler comprising the same, the blister pack assembly comprising a body (3) comprising first and second surfaces each having a plurality of blisters (8', 10') therein which include powder containing medicament.



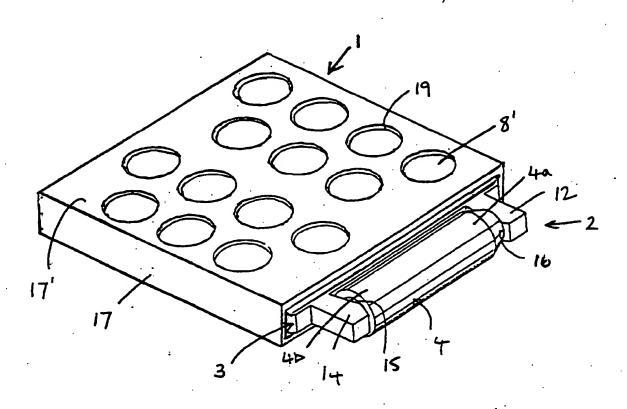
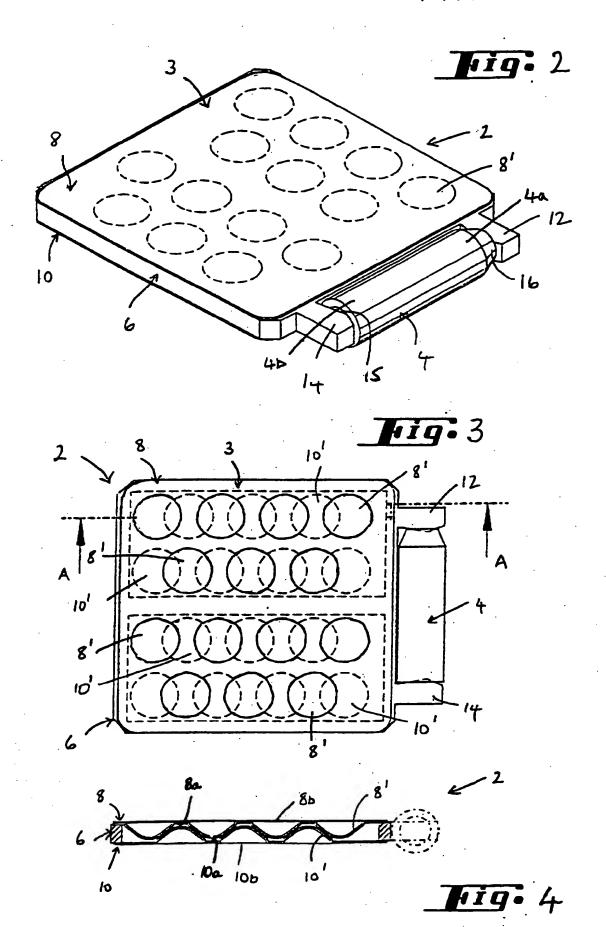


FIG. 1



fry sidit

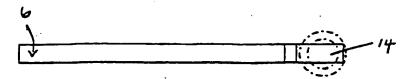
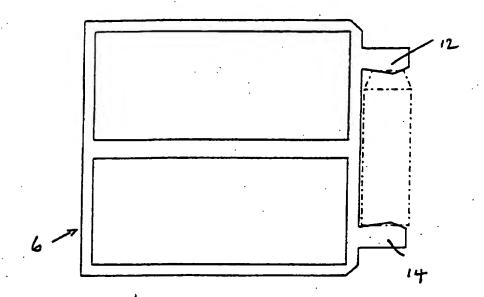
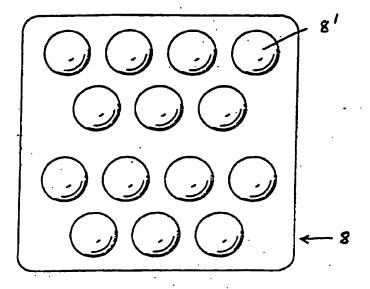


Fig. 5



hig. 6



Hio. 7

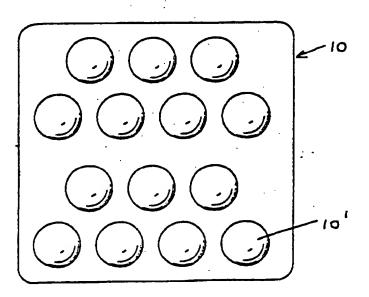
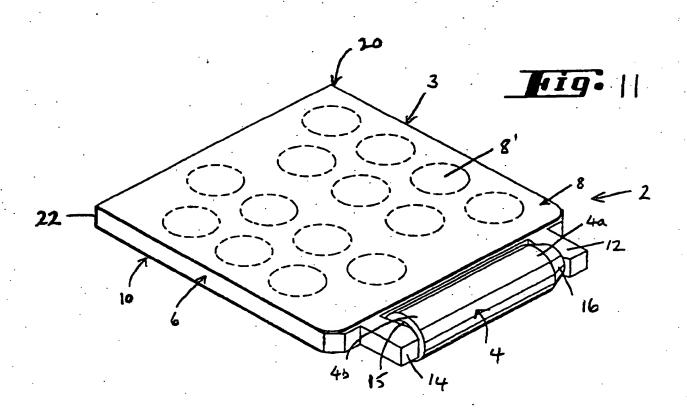
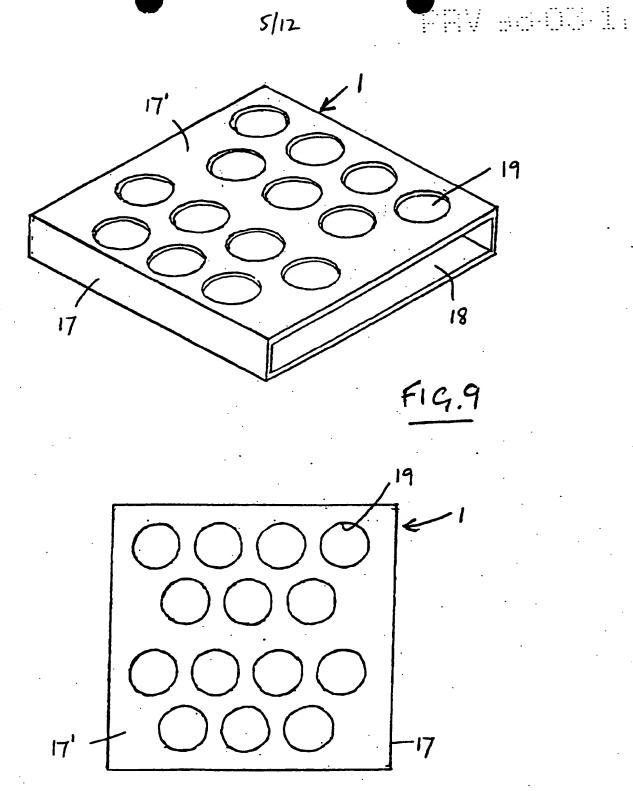
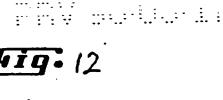


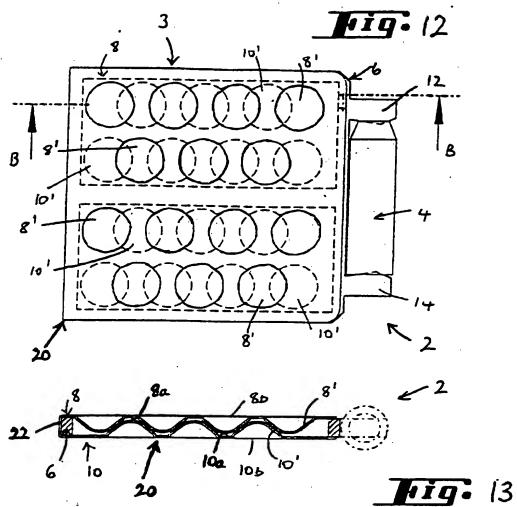
Fig. 8

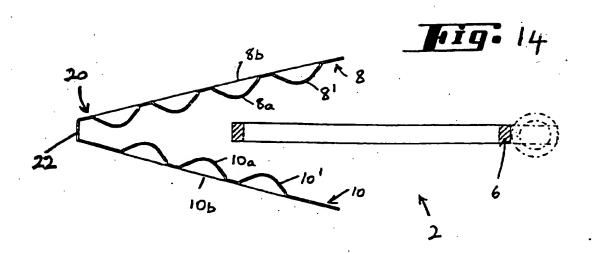


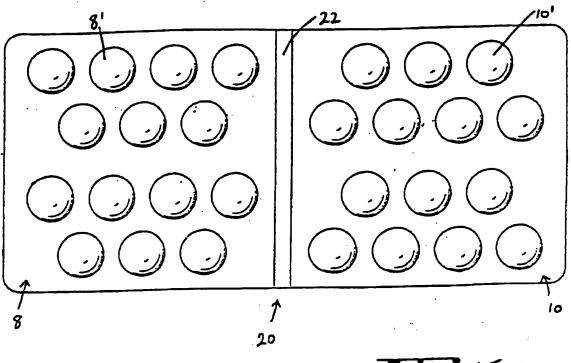


F19.10

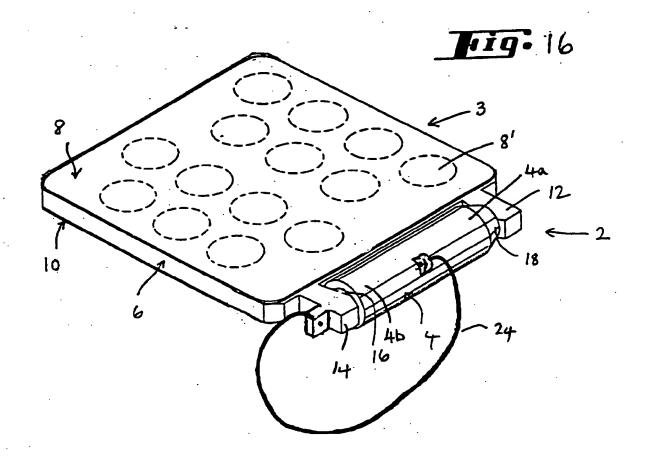


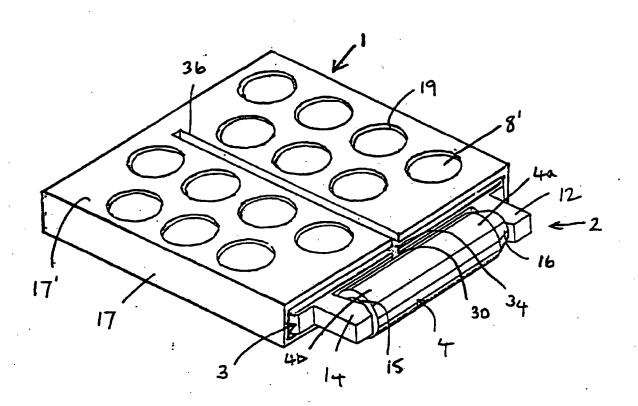




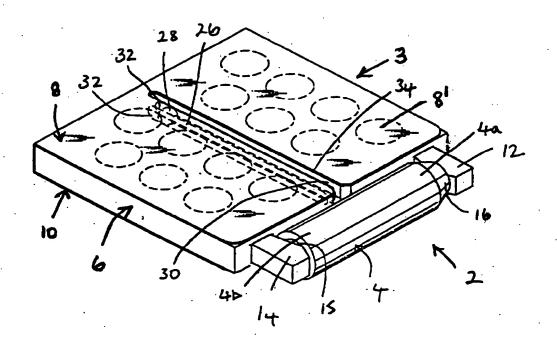




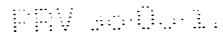


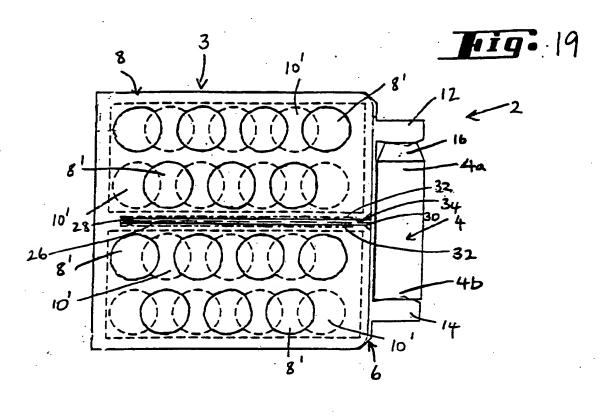


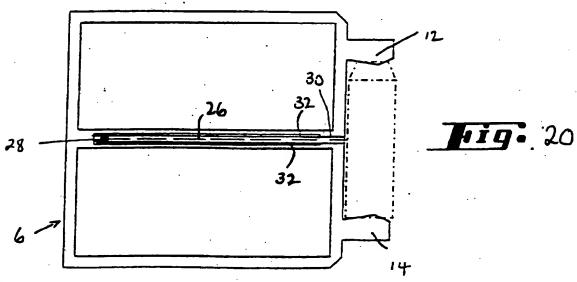
F19.17

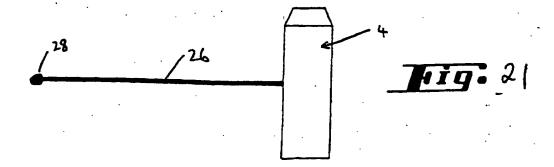


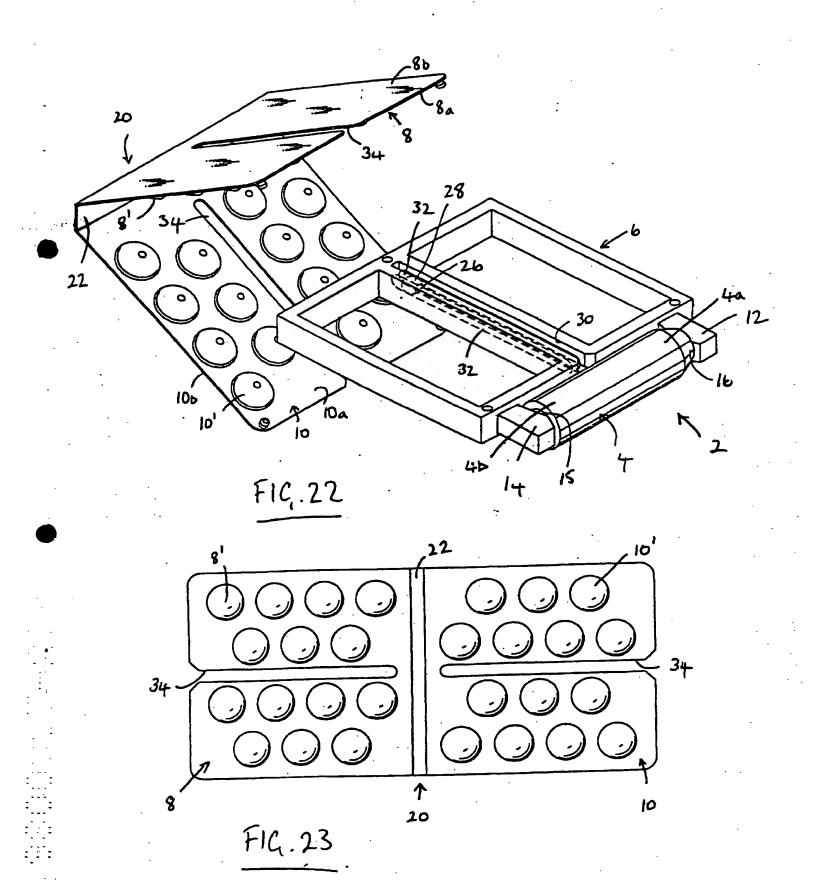
F14.18

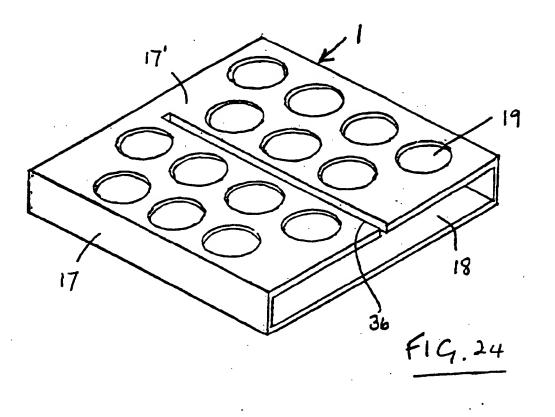


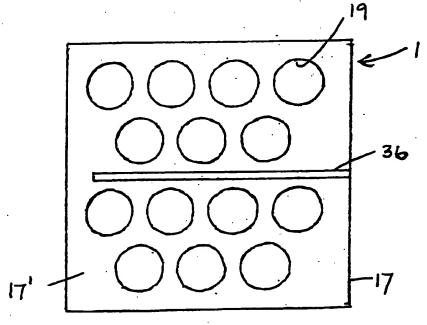












F19.25